

Appl. No. 10/018,018
Amdt. Dated May 17, 2004
Reply to Office action of December 10, 2003

REMARKS

Claims 1-13 are pending in the instant application. Claims 1-11 and 13 are objected to for the use of the terminology in claim 1. Claim 12 is objected to for seeming to claim different types of methods. Claims 1-6 and 10-12 stand rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 5,609,153 to Dumoulin. Claims 7-9 and 13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dumoulin in view of Li et al. and Ranney. The claims have been cancelled and replaced with new claims 13-25. None of the new claims incorporate new matter in contravention of 35 U.S.C. §132.

Reconsideration is respectfully requested.

Previous claims 1 and 2 were combined to present claim 14 for clarity reasons and to address the novelty objection in view of Dumoulin.

Present claim 15 corresponds to previous claim 10 (renumbered only).

New claim 16 was incorporated into the claim set. The claim has its basis in the description (it is referred to the WO-publication no. WO 00/72032 of the application) on page 5, 3rd and 4th paragraph. Previous claim 8 was deleted as being redundant in view of new claim 16.

Present claim 17 corresponds to previous claim 9 (renumbered only).

New claims 18 and 19 were inserted based on the description page 6, line 9 and 10, respectively. Previous claim 13 was deleted as being redundant in view of these new claims.

Present claims 20 to 24 correspond to previous claims 3 – 7.

Present claim 25 corresponds to previous claim 11.

Appl. No. 10/018,018
Amdt. Dated May 17, 2004
Reply to Office action of December 10, 2003

Previous claim 12 has been cancelled, without prejudice.

Claims 1-11 and 13 were objected to for the use in claim 1 of the terminology “e.g. mammalian, avian, or reptilian”. The objection has been obviated by the deletion of this term from new claim 14. Further, the term “patient” was substituted by the term “body” for clarity reasons and the term “whereby to facilitate visualisation of said device in said image” was deleted as this is not a technical feature but only the consequence of carrying out the method as described in present claim 14. Applicants respectfully submit that such an amendment more clearly defines the present invention as applying to any human or non-human with vascularized tissue. Reconsideration and withdrawal of the objection are respectfully requested.

Claim 12 is objected to for seeming to claim different types of methods. Applicants respectfully submit that this objection has been obviated by the canceling of claim 12. Reconsideration and withdrawal of the objection are respectfully requested.

Claims 1-6 and 10-12 stand rejected under 35 U.S.C. §102(b) as being anticipated by Dumoulin et al. This rejection is respectfully traversed.

First, Applicants note that there are two Dumoulin patents cited in the attached IDS (United States Patent Nos. 5,609,153 and 5,479,925) yet the Examiner did not specify to which she referred. Applicants respectfully submit, however, that there is little difference in the descriptions of the two patents, particularly as they might apply towards the instant application.

Applicants respectfully submit that both Dumoulin patents fail to disclose, teach, or suggest either the MR imaging of a device within a body, the use of contrast agents, or the use of a blood pooling agent in MR imaging.

Appl. No. 10/018,018
Amdt. Dated May 17, 2004
Reply to Office action of December 10, 2003

Both Dumoulin patents relate to MRI angiography, or more specifically, the imaging of the vascular system, i.e. the veins, arteries, blood vessels, capillaries etc. Therefore, both Dumoulin patents are directed towards MR imaging of blood vessels (col. 2, line 50 “objectives of the invention), not for imaging the location of a device. A catheter in this context is only used to inject/administer the contrast agent to the patient (col. 4, lines 1-4 and claim 1, step c) “a catheter for routing the polarized contrast fluid …into said subject”). Additionally, both Dumoulin patents fail to disclose, teach, or suggest that its delivery catheter is to be located within the region of imaging at all.

Moreover, the contrast agents Dumoulin discloses are polarised physiological saline solution, polarised blood, polarised whole blood or plasma, polarised blood substitute and polarised blood recirculated from the patients. Without being polarised, these fluids would not give a contrast at all, hence they are not contrast agents per se, but they are made to contrast by polarising them before they are administered to a patient. Col. 4, line 5-16 of the ‘153 patent describes that the fluids lose polarisation and that they have to be delivered to the patient as quickly as possible to retain maximal possible polarisation for imaging, i.e. to be useful as a contrast agent.

The present invention, conversely, provides a method of visualizing an invasive device like for instance a catheter by using MR imaging, which means that the method must be such that the catheter can be seen in an MR image. To achieve this, a blood pool contrast agent is used. These agents remain in the intravascular space, i.e. in the blood vessels during the course of the visualization procedure/MR imaging procedure (page 3, 3rd paragraph) and enhance the contrast between the invasive device and the blood, by which said device can be seen in an MR image (page 3, 3rd paragraph “The effect of the contrast agent is to enhance the relaxation properties of the blood relative to those of the invasive device”). It is hence apparent from the description and also from amended claim 1 that the contrast agent used has to have certain properties.

Applicants respectfully dispute the Examiner’s contention that “the polarized MR contrast agent (of Dumoulin) is inherently a blood pool contrast agent”. This is not true as for

Appl. No. 10/018,018
Amdt. Dated May 17, 2004
Reply to Office action of December 10, 2003

instance saline or blood/blood plasma mainly contain water and salts which easily leak out into the interstitium (the space between the cells) during the time course of an interventional procedure. A blood pool agent however does not leak out as it either comprises of particles like iron oxide which are too big to travel into the space between the cells or chemical moieties which bind to proteins in the blood and which, in turn, keeps them within the blood vessels.

It is therefore clear that neither Dumoulin patent discloses, teaches, or suggests a method for MR imaging of a device used in the body, the use of contrast agents in MR imaging, or the use of a blood pooling agent in MR imaging.

Clearly, as both Dumoulin patents fail to disclose each and every element of the present invention, the present invention is not anticipated thereby. Furthermore, as both Dumoulin patents fail to disclose, teach, or suggest either the imaging of a device, the use of contrast agents, or the use of blood pooling agents, Applicants respectfully submit that the present invention is patentably distinguishable thereover. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 7-9 and 13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dumoulin in view of Li et al. and Ranney. This rejection is respectfully traversed.

Once again, the Examiner has not specified which Dumoulin patent she is referring in the rejection. Once again, however, the two Dumoulin patents disclose substantially the same matter as might relate to the present invention. The Dumoulin patents disclose that a catheter is inserted into a human body. An MR image is created but Dumoulin fails to disclose, teach, or suggest an imaging procedure to create an image of the catheter - only an image of the polarized fluid distributed in the blood vessels of the patient, i.e. an image of the blood vessels. Depending on the nature of the catheter (material), its position in the body, the part of the body imaged and the MR imaging protocol used the catheter may or may not be visible on the MR image obtained. The teaching of Dumoulin addresses the problem of

Appl. No. 10/018,018
Amdt. Dated May 17, 2004
Reply to Office action of December 10, 2003

obtaining MR images of blood vessels (see objects of the invention). The Dumoulin patents simply disclose a method for introducing polarised fluids into a patient.

Applicants respectfully submit that Li fails to correct the above-noted deficiencies of the Dumoulin patents. Li teaches polyatomic clusters which can be used in MR imaging as blood pool agents, as the enhance blood flow images (col. 8, line 9-17). Li is silent about the MR imaging of invasive devices during an interventional or intraoperative procedure. Modifying the teaching of Dumoulin by the teaching of Li would lead to a method of obtaining MR images of blood vessels by using the blood pool agents of Li. A combination of these references would surely work for introducing the Li agents into a patient but such is not the method of the present invention, i.e. a method of obtaining MR images of an interventional device. Hence the prior art references do not disclose, teach, or suggest the present invention.

Ranney similarly fails to correct the deficiencies of the Dumoulin patents. Ranney also teaches polyatomic clusters which can be used in MR imaging as blood pool agents (see abstract “....the carrier complex will preferentially extravasate at locations where blood vessel walls have increased porosity” indicates that the complex will mainly remain in the blood vessels, if they are healthy, which means that the complex could be called a blood pool agent). Ranney is completely silent about the MR imaging of invasive devices to visualize said devices in an interventional or intraoperative procedure. Modifying the teaching of Dumoulin by the teaching of Ranney would again lead to a method of obtaining MR images of blood vessels by using the blood pool agents of Ranney. Hence, the combination of Dumoulin and Ranney would not disclose, teach, or suggest the present invention.

Appl. No. 10/018,018
Amdt. Dated May 17, 2004
Reply to Office action of December 10, 2003

Applicants respectfully submit that as neither Dumoulin, Li, nor Ranney, either alone or in combination, disclose, teach, or suggest the present invention, the present invention is patentably distinct thereover. Reconsideration and withdrawal of the rejection is respectfully requested.

In view of the amendments and remarks hereinabove, Applicants respectfully submit that the instant application, including claims 14-25 are in condition for allowance. Favorable action thereon is respectfully requested.

Should the Examiner have any questions with respect to the foregoing, she is respectfully requested to contact Applicants' undersigned counsel at the telephone number below.

Respectfully submitted,



Robert F. Chisholm
Reg. No. 39,939

Amersham Health, Inc.
101 Carnegie Center
Princeton, NJ 08540
Phone (609) 514-6905

H:\IP\Response to Office Action\NIDN\NIDN10427 (5-10-04).doc